

Applicant: Stinson, J.

Application No: 10/721,702

Response to Final Office Action dated February 20, 2007

Amendment and Response dated April 20, 2007

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REMARKS/ARGUMENTS

Claims 30, 44-59 and 76-84 are pending. Claims 45-49 are withdrawn.

Claim 82 has been amended to describe the bioabsorbable endoprosthesis as, *inter alia*, consisting essentially of a plurality of elongate elements. No new matter is introduced with this amendment. Entry of this claim amendment is respectfully requested.

Section 102/103 Rejections

The claims are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,500,013 to Buscemi et al. (hereinafter "Buscemi"). Applicant respectfully transposes.

Buscemi describes a biodegradable stent 10. (Buscemi, column 4, lines 8-9). The stent 10 includes a main body 11 and a plurality of fibers 18 disposed around the main body 11. (Buscemi, column 4, lines 16-18) (emphasis added). The fibers 18 are described as being annularly wound, braided or woven around the main body of the stent 10. (Buscemi, column 4, lines 32-44) (emphasis added). The fibers 18 may be hollow fibers having an outer diameter not exceeding 0.2 mm and having a wall thickness of 25 to 100 microns. (Buscemi, column 4, lines 7-48, column 4, lines 60-64).

Buscemi, however, fails to disclose, teach or suggest a bioabsorbable endoprosthesis as set forth in amended claim 30, which consists essentially of a plurality of elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of

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the bioabsorbable polymer; wherein the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume.

In other words, Buscemi fails to disclose, teach or suggest that its stent 10 may consist essentially of annularly wound, braided or woven fibers. The main body 11 of the stent 10 of Buscemi is an essential feature of Buscemi's stent 10, and the main body may not be removed from the stent 10 without destroying the intent, function and purpose of Buscemi's stent 10.

Moreover, Buscemi, however, fails to disclose, teach or suggest a bioabsorbable endoprosthesis as set forth in claim 82, which consists essentially of a plurality of elongate elements interbraided into a tubular, radially expandable structure, each of the elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer; wherein the each of the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume; the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure; and the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure. Buscemi is silent as to the relationship of number of filaments and their thickness for a bioabsorbable endoprosthesis.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Hertz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original); MPEP, §2111.3 (8th Ed., Rev. 5

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(August 2006)). Further the MPEP states that “for the purposes of searching and applying prior art under U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, ‘consisting essentially of’ will be construed as equivalent to ‘comprising’.” (MPEP at §2111.3) (emphasis added).

In the present action, the examiner has taken the more expansive interpretation of the “consisting essentially of” phrase. Applicants, however, respectfully submit that clear indications of the basic and novel characteristics of the present invention are present in the subject application such that the transitional phrase limits the scope of the claims to exclude other structures, such as the structures of Buscemi.

The specification clearly describes the basic and novel features of the inventive stent having accelerated degradation achieved by filaments having a reservoir, as follows:

FIGS. 3a-3f illustrate cross-sections of a known member 10....The degradation rate nearer to the surface 14 of member 10 is relatively slower because pH level at the surface 14 is not substantially changes since acid degradation by-products are more readily flushed or diffused away. (Specification page 13, paragraph beginning with “In comparison...”, lines 1-3) (emphasis added)

[F]ilaments [of the present invention] ... advantageously provide accelerated degradation features compared to known materials. The filaments or elongate members have reservoir portions.... (Specification page 14, paragraph beginning with “FIGS. 3a-3f illustrate ...”, lines 1-12) (emphasis added)

Moreover, the specification clearly indicates that such filaments, i.e., filaments having hollow reservoirs, are to be used to form the stent to the exclusion of other stent structures, as follows.

The tubular and self-expandable body or structure form by the interwoven filaments 20, 30, 40 is

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a primary prosthetically-functional structure of stent 10, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures. (Specification page 18, paragraph beginning with “The tubular and ...”, lines 1-4) (emphasis added)

Furthermore, the specification also indicates features that do not materially affect the basic and scope characteristics of the claimed invention, as follows.

However, ... features which enhance or cooperate with the tubular stent and the self-expandable structure or which facilitate the implantation of the structure [may be included, for example] ... radiopaque markers[,] ... a covering or additional interwoven filaments, ... collapsing threads or other structures to facilitate repositioning and removal of the stent. (Specification page 18, paragraph beginning with “The tubular and ...”, lines 4-13) (emphasis added)

Thus, the specification clearly sets forth the basic and novel characteristics of the present invention. Therefore, the action does not properly apply the correct standard to the “consisting essentially of” phrase in the independent claims when considering the applied art. The “consisting essentially of” limitation in the independent claims is a transitional phrase that limits the scope of the claims. As such, this transitional phrase is used to exclude other stent structures, such as the structures of Buscemi, from the scope of the claims.

Thus, Buscemi fails to disclose, teach or suggest the bioabsorbable endoprosthesis as set forth in independent claims 30 and 82. Reconsideration and withdrawal of the rejections of claims 30 and 82, and all claims dependent therefrom, are respectfully requested.

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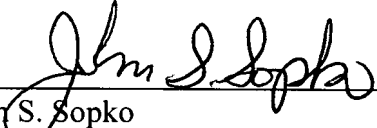
SUMMARY

Therefore, Applicants respectfully submit that independent claims 30 and 82, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

No claim fees or fees for extensions of time are believed to be due with this submission. If any fees, however, are due, the Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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